

ANIMAL DISEASE RISK ASSESSMENT, PREVENTION, AND  
CONTROL ACT PUBLIC HEARING

U.S. Department of Agriculture      September 28, 2001

4700 River Road

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REPORTED BY: Lisa Dennis

P R O C E E D I N G S

MR. MACHEEL: Good morning and welcome to the U.S. Department of Agriculture's hearing on Public Law 107-9, the Animal Disease Risk Assessment, Prevention, and Control Act.

My name is Bill Macheel and I'm a Program Analyst with APHIS' Policy and Program Development staff, and I've been asked to be the presiding officer at this hearing today.

The purpose of today's meeting is to give interested persons an opportunity to provide suggestions and comments regarding development of the final reports required by the Act.

The report will discuss the risks and impacts associated with the potential introduction of foot and mouth disease, bovine spongiform encephalopathy or BSE and other diseases related to BSE and the report will also make recommendations on how to deal with the risks of those diseases to public health and animal health.

The Secretary of Agriculture has formed an Interagency Working Group to help develop this report, and several members of that group are here today to listen to your comments and suggestions. I'll be introducing them in a few minutes.

Your comments today, as well as any written or electronic comments we receive prior to the close of the comment period on October 9, 2001, will be thoroughly considered by the Interagency Working Group as it writes its report.

Now let me go over how we will proceed with the hearing today. As presiding officer, I will announce each registered speaker who has requested to make a statement, and after all the registered speakers have been called, any unregistered speakers who would like to make a statement will be given the opportunity to do so. Please, before commencing your remarks, if you could state and spell your last name for the benefit of the court reporter from Hunt Reporting, who will be transcribing all of the comments made today, and also, we ask that anyone who reads a prepared statement provide me with a copy of that statement and a copy of the transcript will be posted on the APHIS internet website at our <http://comments.aphis.usda.gov> address, and that will be done in approximately 15 working days. A copy of the transcript shall also be made available for public inspection, as part of the public record, at the APHIS reading room, which is at -- in room 1141 of the USDA South Building, 14th Street and Independence Avenue in Washington, D.C.

I'd also like to mention that anyone who is providing testimony today will have the

opportunity to ask clarifying questions about the provisions of the Act and to direct those questions to the Interagency Group members present today. Other than responding to questions about the Act, itself, or how the report is being developed, the group is here only to listen to what you have to say, and they are not planning to discuss today the issues that you bring up concerning the diseases, but will definitely consider them as they write the report.

Today's hearing is scheduled to end at 12:00 noon. I may conclude the hearing before then if all persons who have registered to participate have been heard and there are no other person who wish to speak. Also, if necessary, I may limit the time for each presentation so that everyone is accommodated and all interested persons have an opportunity to participate. As we move through the presentations by the -- by you this morning, I may announce any time limitations or other procedural rules for the conduct of today's hearing if I see that it is necessary. Also, if an individual's comments do not relate to the stated purpose of the hearing, which is to present comments or questions about PL 107-9, it will be necessary for me to ask that person to focus his or her comments accordingly.

Okay, before concluding my remarks, I'd like to introduce the members of the Interagency Working Group seated here in front of the room. To our left here, is Dr. Alfonso Torres, Deputy Administrator for Veterinary Services of the Animal Health Inspection Service. Next is Dr. Daniel Engeljohn of the Regulations and Directives Staff at the Food Safety and Inspection Service, USDA, and that -- and the far end is Dr. Murray Lumpkin, Senior Medical Advisor to the Deputy Commissioner of the Food and Drug Administration.

Okay. I will now call on the first registered speaker to come up to the podium and provide your comments to the public record, and I believe that first person is Dr. Beth Lautner, Vice President, National Pork Board, and Beth for the benefit of the court reporter, if you could

Speak directly into the microphone.

DR. LAUTNER: My name is Beth Lautner, L-A-U-T-N-E-R. Thank you. I am pleased to have the opportunity to present these oral comments on behalf of the National Pork Board for consideration in your report to Congress.

I'm Dr. Beth Lautner. I'm a veterinarian with the National Pork Board and have responsibilities for swine health issues, foreign and emerging animal diseases.

The National Pork Board is a body created by Congress and is responsible for the collection, distribution and program accountability for the pork checkoff. The area of swine health and Foreign Animal Disease prevention falls within the purview of our activities under -- general.

I'm very interested -- our organization is very interested in topic of this hearing as well as myself, personally. I've served on the Secretary's Advisory Committee for Foreign Animal Diseases, The National Animal Health Emergency management Steering Committee as well as chaired committees related to swine health. I've also worked on Animal Health Safeguarding Review.

I'd like to start my oral comments by first commending APHIS for its past commitment to animal health safeguarding and then the recent level of activities that have been heightened in regard to the world situation with regard to foot and mouth disease. I think we should recognize that our current health status is a result of the dedication of the personnel at the State and Federal level and our current policies that have been in place, that have provided the protection that we have today.

The oral comments I make will be provided -- supplemented by more detailed written comments. I just would like to emphasize that it is very significant -- Foreign Animal

Disease is extremely significant to the pork industry. The economic impact would be severe, and these economic impacts would affect not just the producers, but other parts of the chain. The agricultural related businesses, the trade balancing consumers as well, and there is many documented studies that talk about the economic impacts of Foreign Animal Diseases in other countries as well as the data that we have for scenarios that have been done in the U.S., and I would encourage those economic analyses to be included in the report. Both from the other countries, as well as the scenario planning that's been done in this country.

We also would see, for the agriculture related businesses -- there's serious affects on the feed industry, livestock markets, packers, pharmaceutical companies, and private practitioners.

One of the serious economic consequences of a Foreign Animal Disease is the immediate stop of export markets, and this is very serious to the livestock industry. The pork industry -- we export more than a billion dollars, annually. We're the second largest exporter of pork in the world. We recognize that Foreign Animal Disease would result in the loss of those markets, virtually, overnight. We've had some economic studies done and will provide that information on that as well, and recognize that there are -- in addition to that eradication issues and possible eradication -- there are other issues, environmental issues, wildlife effects and social effects. Those areas, should also be highlighted in your report to congress to make sure there is an understanding of the scope of a Foreign Animal Disease encouraging in this country.

As far as risks -- the comments I would like to make on risks would be that many would view the risk as increasing. We have many international visitors. We also have many producers that travel to other parts of the world to look at pork operations, and we have -- we host many tours in this country, as well. Many veterinarians, animal scientists, and students travel

around the world and come back on farms very shortly. With free trade agreements, there is increased trade, and there is an increased potential for a problem to be brought in that way as well. Also, the illegal importation of animals or animal products is an area of concern. Also, we would like to see the report address the potential for bioterrorism to animal populations.

With regard to recommendations, I'd like to bring forward a few. International surveillance is very important. We must know what's going on with regard to diseases in other countries. We must make sure we have the expertise in animal health to gather this information and process it.

We also -- important to provide assistance to other countries to help them deal with a disease in their country, and I think a good example is what's been done with the UK. Providing veterinarians to the UK provides hands-on expertise and assistance as well, to the countries.

With regard to import policies and inspection procedures, we need to make sure that when we set import policies in place, that we have a verification of activities to follow along with those, as well. There should be an annual report that would be provided on how these verifications are taking place, conducted and taking place, as well as evaluating compliance with passage of cargo mail inspection protocols.

With regard to import policies, it's very important that we have a risk assessment capabilities in this country with multi-disciplinary teams to accomplish those in a timely fashion.

With regard to research -- to help prevent a Foreign Animal Disease, it's important that there's close coordination between APHIS and ARS on both short-term and long-term research needs. This is an area that I think needs enhanced working.

As far as surveillance in this country, on the domestic side, we need to have a risk-

based domestic surveillance program for Foreign Animal Diseases. We need to look at how to tie in our State Veterinary Diagnostic Labs as well.

Emergency planning and test exercises. I think we've seen a lot of activity. I participated and other producers have participated in many test exercises. I think we're seeing very good efforts to coordinate our National response with our State and Local response and use the emergency management agencies that are available in the state. We need to continue those and to continue more test exercises on different diseases and more scenario planning and assistance to states in state-based exercises.

Training and awareness is a continual process and we need to continually train our emergency responders, and develop awareness programs for producers, practitioners, allied industry policy makers and the general public.

With regard to response, I mentioned, I think, there is very significant efforts with emergency management agencies and they need to continue in development of response plans.

An area that is important as we have people responding to a Foreign Animal Disease in this country, would be to also have a group that's looking at how we can regionalize our country and be able to resume trade as quickly as is possible and safe. I think plans need to be made now on how we would regionalize our country with regard to disease status. How and who would, specifically, work in that area.

As far as recovery from a Foreign Animal Disease, it is important to have, ahead of time, an understanding of what the compensation would be for producers for losses to Foreign Animal Disease. There is many issues that are under debate and discussion, including compensation issues involved with vaccination for Foreign Animal Diseases, pre-emptive control measures, and animal welfare measures that need to be taken -- restrictions. It's very important

that the government plans for compensation and other opportunities for assistance to producers are clarified, prior to the incursion of Foreign Animal Disease.

One of the questions is related to what are other groups doing, the non-profit and private sector groups, we'll be submitting comments. What we've been doing as far as the National Pork Board, our activities that focused on national coordination, working with USDA and state groups. Working in the Animal Health Safeguarding Review and participating in the Foreign Animal Disease test exercises.

We also are developing plans to -- together State Pork Producers, State Veterinarians, and USDA to talk through some very specific pork issues, as well.

With regard to research, we have provided limited funding with checkoff dollars for foot and mouth disease research and have participated in the reviews of the programs.

We also recognize the need for new facilities for the National Veterinary Services Laboratories, National Animal Disease Center and Center for Veterinary Biologics and the continued modernization of Plum Island.

With regard to education, we have been involved in many efforts, videos, brochures, press releases, a variety of measures to get information out to producers and veterinarians about Foreign Animal Diseases and biosecurity precautions. We've done mailings to over 100,000 producers to get information directly to them, as well as the American Association of Swine Veterinarians, and have created a spot on the website to provide information on Foreign Animal Diseases and biosecurity.

And, to conclude, with regard to private and public sector partnerships, the National Pork Board has been active in the National Animal Health Emergency Management System Steering Committee, which is a partnership with State and Federal, industry, veterinary



societies to look at Foreign Animal Diseases. This group was formed in 1996 and has worked closely together to have each partner recognize their responsibilities in prevention, preparedness, response, and recovery to a Foreign Animal Disease.

I would recommend that a strategic plan that has seven action guidelines, that's been developed by this group, be submitted to Congress, as well. It has very detailed objectives and activities that need to take place for Foreign Animal Disease prevention and response, and I think there's some value to adding that to the report.

Also, the Secretary's Advisory Committee Report from August of 2000, had 15 recommendations. They should be reviewed for their relevancy to be submitted into the report as well.

I would just conclude with -- that a Foreign Animal Disease is -- introduction is very significant. It is something that would be devastating to the industry, and we very much want to see the proper precautions put in place to prevent the introduction, and if there was one, to respond quickly.

MR. MACHEEL: Thank you. Do you have a copy of your testimony? Thanks.

Okay. The next speaker that was signed up was Ross Hamilton, Darling International. Is he here?

MR. HAMILTON: Thank you. I'm Dr. Ross Hamilton, H-A-M-I-L-T-O-N. I'm Director of Research and Nutritional Services for Darling International, Incorporated.

Darling International is one of the largest independent rendering companies in the United States, operating facilities in 22 different states. Darling is also a member of the National Renderers Association, the American Protein Producers Industry and the Fats and Proteins Research Foundation. The National Renderers Association, as well as the American Protein

Producers Industry will also be submitting written comments.

It is the opinion of Darling International that any plan developed by the Department of -- to prevent and contain Foreign Animal Diseases must first recognize the importance of the rendering industry in disease prevention, control, and eradication efforts, and secondly, regulate the disposition of dead animals and unprocessed viscera, bone, fat trim, meat trim, blood, feathers and other animal products or by-products that are deemed to be inedible or unsuitable for human consumption, and these, for the rest of my presentation will be referred to, collectively, as raw materials.

Each year the United States rendering industry provides a vital service to society by removing and processing the more than 50 billion pounds of animal and poultry by-products generated by the livestock, poultry, and meat processing and retail meat industries. Unprocessed raw materials contain more than 60% water, on average. Most of this water is removed by the rendering process, which markedly reduces the volume to approximately 18 billion pounds, making it easier to use or dispose of. The principal finished rendered products are fats and proteins, which at the present time are used primarily in animal feed and oleochemical industries around the world. Without the rendering industry, raw materials would accumulate and seriously impede the entire meat production and poultry processing industries. These materials would have to be discarded or disposed of in community landfills, incinerators, or worse, left in illegal dumping sites, which potentially would cause public health hazard. Properly prepared, the volume of raw materials generated in one year in this country would take up more than 25% of the existing landfill space available.

The rendering industry does not collect and process all of the raw materials produced in this country, which is a potential concern. This problem may be further exacerbated

because a growing percentage is disposed of in an unprocessed state. Raw materials are being improperly disposed of in garbage bins destined for landfills, road ditches, or waterways in sparsely populated areas and compost piles, operated by unlicensed individuals. The prevailing commodity market and economic conditions within the animal production, meats and rendering industries precipitated this trend.

Unless properly processed in a timely manner, raw materials provide an excellent environment for disease causing organisms to grow and potentially threaten animal health, human health and the environment. If allowed to accumulate and decompose unchecked, these tissues would become a substantial biohazard, promoting disease, attracting and harboring rodents, insects, scavengers and other recognized disease vectors and attracting predatory animals into densely populated areas.

Except for incineration, which is cost prohibitive and environmentally unsuitable, the alternatives to rendering for the disposal of raw materials do not provide adequate biosecurity. The origin and ultimate disposition of raw materials are not traceable when methods other than rendering are used. This is problematic when attempting to prevent, control or eradicate any disease. Only rendering companies are held accountable and required to document and maintain written records suitable for government agencies to trace raw materials back to their source as well as trace finished products forward to the end-user, and this is provided -- mandated by the FDA in 21 CFR 589.2000.

Domestic and wild animals may contract disease from unprocessed or improperly processed raw materials. Direct or individual exposure to improperly buried dead animals and run-off from compost piles and landfills are some of the routes of potential exposure. When raw materials derived from ruminant animals are disposed of by methods other than rendering, their

disposition is not regulated and the potential exists for cattle and other ruminant animals to be exposed to materials prohibited by the FDA in 21 CFR 589.2000. For example, spreading composted raw materials, of ruminant animal origin, on land used for grazing and or hay production is permissible under the current regulations. The only way to insure that raw materials are biosecure is to regulate their disposition and require that licensed rendering companies or other appropriate regulated entities collect, transport and process these materials.

Darling International and the US rendering industry take biosecurity very seriously and recognize that rendering has a pivotal role in protecting animal, as well as human life. Darling International, Incorporated and the US rendering industry fully support the current BSE prevention efforts developed by the FDA, APHIS and other Federal agencies, even though no case of BSE has ever been ever found in the US.

Rendering facilities are permitted and licensed by the states in which they operate to collect, transport and process raw materials. State and Federal agencies routinely inspect rendering facilities for compliance to applicable regulations, finished product safety and feed ingredient quality. Only the rendering industry has the necessary infrastructure in place to allow traceability of raw materials, finished products and by-products and insure compliance to Federal and State regulations and tolerances.

Full-service rendering companies are fully-capable of handling raw materials as well as assisting in animal disease prevention, containment and eradication. The rendering industry is an effective method for insuring biosecurity because processing conditions and volumes, raw material characteristics and drying create an unfavorable environment for viruses, bacteria and other microorganisms to survive and grow. The temperatures used, which typically exceed 270 Fahrenheit, in the rendering process are more than adequate to inactivate or kill most

know pathogenic organisms, with the possible exception of the agent that causes BSE. Further, the water activity of finished products is, generally, considered to be too low to allow pathogens, such as Salmonella, to proliferate. For these reasons, the rendering industry has been instrumental in mandatory as well as voluntary disease eradication control efforts for many years.

Pseudorabies eradication efforts are the most recent example of the rendering industry's value in disease eradication and control. Using the State of Iowa as an example, the number of Pseudorabies positive herds declined from more than 4,000 infected herds to fewer than 40 because of this voluntary program.

Recent events have further increased national concern about the potentiality for a biological catastrophe that would impact the nation's livestock and poultry industries. The rendering industry recognizes that the United States must be prepared to address the consequences of such an event by utilizing every possible means of control and prevention that is available. To that end, it is vital that the Department and the other agencies involved, recognize that the rendering industry represents one of the nation's most efficient means in controlling and preventing the spread of diseases associated with animal tissues.

Darling International, Incorporated urges members of the various agencies involved in developing any national biosecurity plan to utilize the rendering industry to its fullest potential and to regulate the disposition of raw materials and required that licensed rendering companies or other appropriate regulated entities collect, transport and process these materials.

Thank you.

MR. MACHEEL: Do you have a copy of--

MR. HAMILTON: Yes.

MR. MACHEEL: Okay. The next speaker signed up was Francis Amchimbloss

from Antec International. Is he here?

Mr. AMCHIMCLOSS: I'm here, but nothing to speak of.

MR. MACHEEL: Okay.

MR. AMCHIMCLOSS: I'll make some comments later, but not --

MR. MACHEEL: Great. Thank you. Okay. The next person is Steve Roach, Food Animal Concerns Trust.

MR. ROACH: Hello, my name is Steve Roach. And that's R-O-A-C-H.

Food Animal Concerns Trust, FACT, is a non-profit organization that advocates better farming practices to improve the safety of meat, milk, and eggs. FACT has participated in developing the Federal Government's response to the threat of BSE to US agriculture, since the disease was first recognized. FACT was at the table when a Federal strategy to keep US cattle free from bovine spongiform encephalopathy, BSE, was fashioned several years ago, and FACT worked on the drafting of the FDA rule to prohibit ruminant protein from ruminant feed.

FACT's focus is on protecting the American consumer from food safety hazards, so these comments will be directed, primarily, towards BSE, instead of foot and mouth disease, which has little potential to directly impact human health. Protecting the American public from BSE is a difficult task given the uncertainties about the nature of the disease and its methods of transmission. At this time, there are basic questions that have not been answered including a lack of certainty about the transmissible agent. There are also troubling gaps in our understanding of how transferable this and other transmissible spongiform encephalopathies, TSEs, are between species. Given these serious gaps in our understanding, any risk assessment will necessarily be speculative and with a large margin of error. What is clear though, is that the industrial scale practice of feeding farm animals to other farm animals has the potential to multiply this type of a

disease even where the amount of infective material is, initially, very low or the infectivity is also low.

These comments focus on four overlapping areas of the Federal response to the BSE problem. Number one, prevention of the introduction of BSE from sources outside of the US. Two, surveillance for BSE within the US. Three, control of the potential spread of BSE in the US, and four, necessary research. FACT commends the USDA and the FDA for the work they have done in each of these areas, but we feel there is much more that could be done.

Current controls aimed at reducing the risk of introducing BSE into the US animal feed supply focus on restricting the imports of live animals and animal feed from countries with a high risk for BSE. This is an appropriate response, but so far, has not been broadly enough applied. Over seventy countries received shipments of feed from the UK while they were inadequate controls on the spread of BSE in the production of animal feed. With a few exceptions, the US has placed restrictions on the importation of feed containing animal products only from European countries. Because of the difficulty in detecting the disease before its advanced stage, it is imprudent to wait until a country has suspected cases of the disease before restricting imports of animal feeds. Japan was placed on the list of restricted countries only after a suspected case was discovered. The US needs to do a better job of determining which countries are a potential source of BSE infection. This is, particularly, important given the difficulty of enforcement of feeding restrictions once feed has entered the US. FACT recommends that a careful review of the procedures for determining which countries are at risk for BSE. The evaluation of the risk should be frequently updated as new information becomes available and as our understanding of the disease increases. Considerable effort should be placed on determining where the next outbreak of the disease will occur. In addition to this, I think what the US

Government really needs to do is help with surveillance in other countries.

So far, we've focused on the concern with Europe, but there's probably a greater risk in the developing world where there aren't going to be the controls placed by the country, itself. So, if US could also help other countries with the surveillance programs, that would be a big help and probably necessary.

Okay. Surveillance efforts in the US have focused on sampling cattle felt to be at greatest risk for BSE. FACT agrees that sampling should be carried out on at risk cattle. Our concern is that the numbers of cattle tested are too small. APHIS has not stated on what basis it has set its targets for surveillance. It has only indicated that these targets are a multiple of the standards set by the International Office of Epizootics, OIE. It must be noted that in setting these standards, OIE states that these values are not scientifically determined, but are a subjective judgement. The European Union has found that a much higher level of surveillance is necessary. FACT calls upon the USDA to develop a more rigorous surveillance program. USDA needs to justify the level of testing planned and explain what level of BSE in the US it could be expected to detect.

Current controls aimed at reducing the threat of spreading BSE in the US utilize controlling the feeding of ruminant derived proteins to ruminants. FACT agrees that controlling the use of animal products in animal feed is the best way to limit the spread and multiplication of BSE and other TSEs, but we are concerned that the current program does not provide sufficient monitoring and enforcement of the current rules. Further, FACT believes that the current controls, even if properly enforced, do not sufficiently limit the types of feed that can be fed. In recent reports of inspections to renderers and feed processors by the CVM, Center for Veterinary Medicine, approximately 20 percent of all categories of inspected facilities were out of



compliance. This shows that the US feed industry has yet to take the threat of BSE seriously. FACT calls upon the FDA to step up enforcement to insure that all firms come into compliance. We are, particularly, concerned about two areas where there is greatest risk for the breakdown of the control system. First, there -- first where there is risk -- okay. First, there must be stepped-up monitoring of plants that mix feed for both ruminants and non-ruminants in order to ensure that there is not the commingling of ruminant and non-ruminant feed. The second area of concern is with the unknown number of locations where feed is mixed on farm. A system must be developed to monitor these farms for compliance as well.

In addition to increased enforcement of compliance with the existing rules, FACT believes that the controls on animal feeding need to be extended. Given the uncertainty about the method and mode of transmission and given the lack of understanding of the between species barriers to the transmission of BSE and other TSEs, FACT recommends the following further restrictions on feeding. Because there is still great uncertainty about the transmissible agent for BSE, FACT recommends that all ruminant proteins be banned from feeding to other ruminants, except milk and milk products. FACT feels that the exemptions for blood and gelatin should be removed until they are shown, conclusively, not to carry any risk of spread of BSE. In addition, because of the clear evidence of the potential to transfer TSEs between species -- TSEs -- BSE has been shown to be able to infect felines and mice and humans if we accept that the Variant Creutzfeldt-Jakob Disease is related to BSE, which is most likely. So there is very clear evidence that these type of transmissible spongiform encephalopathies can be transmitted between species. So that -- there is that clear risk, and we don't really know how much of a risk it is. We recommend a restriction on the use of any animals with neurologic disorders as feed for any livestock, including poultry, equines, and swine. So, if the animal dies from neurological disorder,

there is a great risk if we go ahead and feed it to another animal.

Similarly, the use of materials from the bovine central nervous system should be banned along with the use of bovine materials from any countries with a high risk for BSE for any animal feeding purposes.

The final area where much work needs to be done is in research on BSE and other TSEs. FACT believes that the highest priority is to develop a test that can detect BSE in live animals. The test we were able to detect BSE in live animals, would also have to be a rabbit test. That is inexpensive, so that we could, actually, apply it to a large number of animals. We feel that this is absolutely necessary for a truly effective surveillance program. Other areas that need further research support are basic research into the nature of prions and their infectivity. Finally, much more effort must be given to understanding the differences between the various TSEs and the species barriers between them. We feel that a serious look must be given to the potential spread of BSE or another TSE in the swine population.

We appreciate the opportunity to present these comments and we shall also be submitting further comments in a written form. Thank you.

MR. MACHEEL: Thank you. Do you have a copy? All right. Thank you.

The next speaker that contacted me was Robin Wiley. Is Robin here? Give your name and also spell your --

MS. WILEY: My name is Robin Wiley, and I'm representing Timberline Foundation.

MR. MACHEEL: How do you spell it?

MS. WILEY: Like it sounds. Timberline.

MR. MACHEEL: No, your name.

MS. WILEY: Oh, W-I-L-E-Y.

On behalf of the Timberline Foundation, I wish to commend the US Department of Agriculture for its initiative in holding today's hearing and, in particular, for its efforts to establish and implement a chronic wasting disease program for live elk herds in the United States. Establishments of such a program is an essential first step towards the eradication of chronic wasting disease, a disease impacting both native and farmed elk populations in the US.

The Timberline Foundation is an Oklahoma non-profit corporation founded in 1990 with the primary purpose of the research and development of solutions to disease affecting elk. Timberline is managed by persons both sensitive to the welfare of elk and actively engaged in the elk industry and academic community. The foundation has made a commitment to seek funds to develop a live animal test for chronic wasting disease in elk and is participating with Oklahoma State University in the development of a research project to perfect such a test for the disease.

CWD is a progressive, fatal disease of the central nervous system of cervids, such as mule deer, whitetail deer, and elk. It is a type of transmissible spongiform encephalopathy; (I'm sure everybody knows that. I can't pronounce it.) The symptoms and pathologies are similar to mad cow disease.

Chronic wasting diseases has its origins in the state of Colorado, where infected deer and elk were released into the wild near Fort Collins, Colorado. The CWD infected animals released by the Wildlife Department spread the disease to resident populations and now wild deer and elk herds around the point of release are infected with CWD. Colorado Fish and Game has announced plans to reduce the wild deer herd population north of Fort Collins by 50 percent. However, this gives no assurance that the disease will be either eradicated or eliminated. There are, currently, three domestic elk herds in Colorado, Nebraska and Oklahoma known to be

afflicted with the disease. As the origin of CWD in these impacted herds is not known, efforts to trace back the disease to its point of origin will involve a substantial effort. For the domestic elk industry, this may quickly evolve into a matter of epidemic proportions.

At the present time, there is not test that can be performed on a live animal that will determine if the animal is infected or carrying the disease. There is no early determination of the disease and the current protocol is to wait for an animal to exhibit symptoms and then either slaughter or quarantine that animal or any animals in close contact. A live animal test must be developed in order to manage and, ultimately, eradicate the disease. If such a test is not developed, millions of dollars will have to be spent to indemnify owners of healthy animals that are slaughtered in the process. Many whole herd eradications have verified but one or two infected animals in the entire herd, and yet the whole herd is subject to slaughter.

The Timberline Foundation wishes to use one of the few remaining infected herds as a research tool to develop a live animal test for the disease that will indemnify infected animals as well as those at risk of carrying the disease. The owner of the herd, the elk industry, and members of the academic community are committed to join forces. First, to develop a live animal test to determine infected animals, and second, to eradicate the disease in farmed elk and deer populations.

The Timberline Foundation has secured private funding to begin this research, and would welcome any additional funding available through APHIS for the conduct of this research. The Timberline Foundation thanks APHIS for the opportunity to testify this morning, and looks forward to working with APHIS towards the development of a live animal test which would eradicate chronic wasting disease. Thank you.

MR. MACHEEL: Thank you. Do you have a copy of your --

MS. WILEY: Yeah.

MR. MACHEEL: Our next speaker is Karen Egbert, Center for Science in the Public Interest. Is Karen --

MS. EGBERT: Good morning. My name is Karen Egbert, E-G-B-E-R-T, and I am a Senior Staff Attorney in the Food Safety Program at the Center for Science in the public Interest.

First of all, I'd like to thank the Service for providing us the opportunity to comment on the report it must provide to Congress under the Animal Disease Risk Assessment, Prevention and Control Act of 2001.

In fact, we've already filed our written comments, but I would like to highlight a few of the things that CSPI feels are particularly important to include in the final report.

Although USDA and FDA have taken important steps, important pro-active steps, to reduce the risk that BSE, FMD and related diseases could be introduced into the United States and spread within the country, there is more that can and should be done.

A little over two weeks ago, the first suspected BSE case in Japan -- apparently, the first in all of Asia, was discovered. This episode demonstrates that the USA cannot be complacent about our current protections and must be prepared by taking certain steps. First and foremost, USDA should conduct a complete and comprehensive review of all regulations, directives, and purchasing specifications, including for the school lunch program, to ensure that if BSE were ever found in US cattle, no BSE-infected material can enter the food supply. This means that, among other things, FSIS should amend its regulations to ban beef slaughter and processing operations from using spinal columns and neck bones in Advanced Meat Recovery or other systems that mechanically separate meat from bones. In fact, we have filed a petition with

FSIS asking for this action.

Second, although we do have a mammalian-protein feed ban in place, FDA needs to strengthen its enforcement. In particular, FDA must strengthen prohibitions to assure there is no commingling and cross-contamination of different types of feed that could result in cattle eating the banned feed.

The July 2001, review of the origin of BSE by the Working Group of the European Union's Scientific Steering Committee found that the BSE agent was so infective that accidental contamination of cattle feed with pig or poultry feed containing meat and bone meal was a significant factor which continued to spread BSE after the UK ban on the use of meat and bone meal in cattle feed.

Recent compliance statistics show that only about three quarters of the inspected feed mills, ruminant feeders, and renderers were in compliance with the requirements of the feed ban and about 85 percent of the 180 renderers handling prohibited materials were in compliance. We need to strive for 100 percent compliance and the report should identify ways in which FDA intends to do that.

On another front, imports -- APHIS and FSIS must act immediately to strengthen the import-inspection firewall. It should do this by updating their surveillance, monitoring and inspection systems over imported meat products.

The recent audit by the Department's Office of Inspector General has identified numerous deficiencies that could allow imported meat products from countries with FMD and BSE restrictions into this country. Therefore, we recommend that APHIS must act now to update its ability to track imports by developing a centralized record-keeping system. FSIS and APHIS must also work to improve communications between the two agencies and their respective field

offices, and again, this is a recommendation in the audit.

Finally, the report should include certain recommendations for Congressional legislation to strengthen the enforcement authorities of the federal agencies with responsibility for protecting US herds and consumers' food supply. These include the authority to recall potentially contaminated products. Authority to trace illness-causing animals and food back to the farm, the trace back authority, and authority to seek mandatory civil penalties for violations of food safety regulations.

Thank you very much for allowing us the opportunity to present our views.

MR. MACHEEL: Thank you. That's -- those are the people that had contacted me earlier to speak. Is anyone else -- would anyone else like to speak today? Yes.

MR. GOELDNER: I'm Dean Goeldner from the American Veterinary Medical Association. It's G-O-E-L-D-N-E-R.

The AVMA will be submitting their formal comments in writing. So, I just wanted to briefly, reemphasize a couple of points you've heard already, earlier this morning.

First of all, to commend APHIS and CBM for the work they've done in keeping BSE and foot and mouth disease out of this country, but also to emphasize the points that you heard about the -- excuse me -- about the need for additional research to find out the way that transmissible spongiform encephalopathies are transmitted. The tremendous need for a live-animal test, and also the bioterrorism threats that we see in the country now. All, I think, emphasize the importance of improving the facilities at Ames, Iowa, and so, we would like to encourage you in your report to emphasize the importance of the planned improvements for those facilities for APHIS and ARS, and we can address some of these important needs. Thank you very much.

MR. MACHEEL: Thank you. Any one else who would like to speak?

MS. BECKER: Leah Becker. It's spelled L-E-A-H, B-E-C-K-E-R. I'm with the National Pork Producers Council.

The National Pork Producers Council appreciates you holding this public hearing and the opportunity to give oral comments. We also will be filing more extensive written comments to the docket.

I am a Government Relations Representative handling legislative and regulatory issues with Animal Health and Safety and Research. I do the coordination for the animal agriculture coalition. I've participated in the Animal Health Safeguarding Review on the Exclusion Subcommittee, and I'm also a member of the National Animal Health Emergency Management Steering Committee.

The National Pork Producers Council is the public policy arm of the Pork Industry to dovetail off of the checkoff arm of the National Pork Board. So, to broaden a little bit from the comments that you heard from Dr. Beth Lautner, I will just go a little bit further than what she said.

The US pork industry, first of all, is grateful for the work that your agencies do to protect the health of our US swine herds and all of animal agriculture. The industry is dedicated to protecting our herd health and also being prepared to detect and respond to an outbreak of a Foreign Animal Disease here in the United States. We are committed to continuing to work with your Federal agencies, states, veterinarians and the animal agriculture industries to ensure this system is in place and functioning properly.

As -- in the height of the UK foot and mouth disease outbreak, our Board of Directors decided to take a step further to protect us from the introduction foot and mouth



disease here, and we cancelled our World Pork Expo which is our Tradeshow that we expected approximately, about 40,000 US pork producers and consumers, and about 2,000 international pork producers from 60 different countries. We took this as a step to further protect our country and then also urge some different recommendations from members of Congress, USDA, pork producers and other livestock organizations, and I'll just briefly mention those.

First of all, 100 percent compliance of inspection protocols by USDA, APHIS and the US Custom Service on all passengers, mail and cargo in the countries that are foot and mouth disease positive.

We encourage all pork producers and pork plants to prohibit foreign visitors from touring farms and plants. Increase funding to USDA, APHIS for prevention of Foreign Animal Diseases, particularly foot and mount disease. Increase funding for USDA, APHIS for increased detection and response on Foreign Animal Diseases. Strongly encourage the US Government to take all appropriate actions to eliminate the accidental or intentional pathways of the introductions of Foreign Animal Diseases.

While we realize that 100 percent inspection of passengers and cargo from countries that are foot and mouth disease positive is not possible, we do ask that the USDA and the US Customs Service continue to try to achieve 100 percent compliance with the directives to the field on inspection protocols of he international passengers, mail and cargo from these countries. During the height of the foot and mouth disease outbreak in the UK, we would hear accounts from passengers and we continue to hear accounts that were not sent to agriculture for inspection and if they were, that they did not disinfect their shoes or they didn't have the disinfectant to do that. We have relayed these accounts on to your officials for review, and we will continue to do this, and urge that they are fully implemented.

We urge that risk assessments and pathway analysis need to be completed to review all possible pathways and the appropriate action taken to protect our US swine herd from the introduction of Foreign Animal Diseases into this country. This needs to be conducted for both accidental and intentional pathways

USDA needs to strongly support and encourage the passage of the Animal Health Protection Act. This is needed to consolidate and modernize the APHIS animal health legal authorities. Passage of this legislation is vital to give the Secretary of Agriculture clear authority to respond quickly to an animal disease, such as foot and mouth disease, be it introduced accidentally or intentionally into the US. Equality and authority with the Plant Protection Act, that was passed in 2000, is needed to deter illegal importation of restricted animals and animal products into the US.

The National Pork Producers Council is also very supportive of the modernization of the facilities in Ames, Iowa and at Plum Island. We need up-to-date research facilities and diagnostic capabilities to help insure that the systems are in place to respond to disease outbreaks and protect the safety of our national meat supply, and allow the US to continue to compete successfully in a global market place, and we urge continued coordination between APHIS and ARS at these facilities.

Again, thank you for the opportunity to comment and we will be providing further recommendations in a written testimony.

MR. MACHEEL: Thank you. Would anyone else like to speak?

MR. HODGES: My name is Jim Hodges with the American Meat Institute, H-O-D-G-E-S.

Like other speakers this morning, I had no planned to make oral comments, we

will be submitting our written comments to the record, but based upon the time that we have, as well as the previous comments, I'd like to make two or three points.

The American Meat Institute is the national trade association representing meat and poultry processors throughout the nation, and in North America. Our members -- we're the oldest and largest trade association representing the manufacturing sector of the livestock industry. Our members slaughter in excess of about 90 percent of all of the beef, cattle, hogs, sheep, chickens, and turkeys in the United States. Millions of animals pass through our facilities each and every day, which requires packers to be intimately involved in any animal disease control efforts.

Our desire, which is obvious, but probably deserves restating, is that all reasonable precautions to prevent the introduction of Foreign Animal Diseases in the United States. Diseases such as BSE and foot and mouth disease will have a devastating affect on our industry, both domestically and in our export markets, and as many of you are aware, our export markets are becoming more and more crucial to moving our industry forward economically.

I would complement the regulatory agencies, in that, in our opinion, all of the agencies, APHIS, FDA, and FSIS have done an admirable job in preventing the introduction of Foreign Animal Diseases. We can always be critical and look for improvements, which we should, but I think in the bottom line, we need to applaud the efforts of our Federal Government, because we do not have foot and mouth in this country. We do not have BSE, and that is the ultimate proof of whether those systems are working or whether they're not. That's not to say that we shouldn't continually evaluate those and move forward, but taking precipitous actions based upon some kind of theoretical threat without some kind of documented risk benefit, seems to us to be going in the wrong direction.

Concerning contingency planning for if a disease comes into the -- this country, and again, here we're focusing, primarily, on BSE and foot and mouth, but other diseases would be put in this category, we would ask that the agencies be more aware of packers or their trade associations. They need to be intimately involved in any kind of disease eradication efforts or disease transmission programs as -- because of the numbers of livestock that we handle. To often, at least in our opinion, we think about the live animal and the disease, but we have an awful lot of products in our plants too, and those products are distributed throughout the world. So, depending on the nature and extent of the problem, we would urge all of the agencies to think not only about the live animal and the producer interest, but think about the manufacturing interest and what that means. That comment is not to be critical, we just think it needs to be emphasized.

Finally, a comment, Federal Inspectors from the Food Safety Inspection Service Center are in our slaughter facilities constantly. Every single day, they have to be there when the plant is operating, and we would urge that there be better cooperation between the Animal Health Inspection Service and the Food Safety Inspection Service, particularly, as it relates to disease surveillance. There is cooperation today, but I think it needs to be improved, particularly, as it relates to the collection of biological samples that may be submitted to the APHIS Disease Laboratories. Obviously, there's a question of manpower, resources, and all of that, but it -- to us there seems to be an opportunity for improved efficiencies in our slaughter facilities if we better utilize the FSIS veterinary personnel in disease surveillance and sample collection. We will leave that to the agency to work out that our desire is to improve that cooperation for timeliness, logistics, costs, and a variety of other reasons.

Finally, thank you very much for opportunity to present these comments and we will submit some written comments.

MR. MACHEEL: Thank you very much. Other speakers? Okay, if not, thank you all for coming, and as I mentioned, we will be putting the transcript onto our website once it gets completed by the court reporter. So, look for that, and again, thank you all for coming.

(Whereupon, at 10:05 a.m., the meeting was adjourned.)